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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,819	06/14/2007	Samuel K. Sia	H0498.70211US02	5917
	7590		EXAMINER	
600 ATLANTIC	C AVENUE		YU, MELANIE J	
BOSTON, MA 02210-2206			ART UNIT	PAPER NUMBER
			1641	
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			10/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/584,819	SIA ET AL.				
Office Action Summary	Examiner	Art Unit				
	MELANIE YU	1641				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 66(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. ely filed the mailing date of this communication. O (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on <u>27 Ju</u>	ne 2006.					
/ <u> </u>	action is non-final.					
3) Since this application is in condition for allowan	nce except for formal matters, pro	secution as to the merits is				
closed in accordance with the practice under E	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-71</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1-71 are subject to restriction and/or e	election requirement.					
Application Papers						
<u> </u>	r					
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Ex	• • • • • • • • • • • • • • • • • • • •	• •				
Priority under 35 U.S.C. § 119		, (61,61, 61, 161, 171, 176, 162,				
		(-1) - · · (5)				
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(a) or (t).				
a) ☑ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents		on No				
2. Certified copies of the priority documents						
	3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau		٨				
* See the attached detailed Office action for a list of	or the certified copies flot receive	u.				
Attachment(s)	_					
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P					
Paper No(s)/Mail Date	6) Other:					

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18 are drawn to a method comprising the special technical feature of determining the transmission of light through an opaque material.

Group II, claim(s) 19-25 are drawn to a product comprising the special technical feature of an antibody immobilized on a chamber substrate.

Group III, claim(s) 26-44 are drawn to a method comprising the special technical feature of flowing a metal solution over a surface.

Group IV, claim(s) 45-55 are drawn to a method comprising the special technical feature of accumulating an opaque material on a portion of a surface.

Group V, claim(s) 56 and 57 are drawn to a product comprising the special technical feature of instructions for performing an assay.

Group VI, claim(s) 58-71 are drawn to a method comprising the special technical feature of illuminating bound sample with a pulse modulated light.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: groups I, III, IV and VI are drawn to methods that do not share a special technical relationship. Groups II and V are drawn to products that do not share a special technical relationship.

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Furthermore, the application contains method and product claims to more than one of the combinations of inventions as set forth by 37 CFR 1.475.

According to 37 CFR 1.475 regarding unity of invention:

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution with each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings.

The methods recited in groups I, III, IV and VI do not share a special technical feature that defines a contribution over the prior art. Geddes et al. (US 2006/0147927) teach a method comprising: flowing a fluid sample over a surface (sample with target

biomolecule is contacted with immobilized capture biomolecule, par. 22); allowing a sample component to bind with a binding partner disposed on the surface (immobilized capture biomolecule attached to metallized surface, par. 22) and accumulating an opaque material on a portion of the surface (immobilized metallized surface provided, par. 22).

The products recited in groups II and V do not share a special technical feature that defines a contribution over the prior art. Geddes et al. (US 2006/0147927) teach a chamber having a surface having an antibody disposed on a portion of the surface (capture probes immobilized to silver colloids on substrate, par. 67; capture probes may be antibodies, claim 11) and an opaque layer associated with the portion of the chamber (surface bound silver colloids form substrate, Fig. 1; capture probe immobilized to opaque, silver surface, par. 67).

Applicants are allowed at most one product, one method of making and one method of using in a single general inventive concept. However, the product, method of using and method of making of groups I-VI do not form a general inventive concept because they do not share a special technical feature over the prior art. Geddes et al. (US 2006/0147927) teach a chamber having a surface having an antibody disposed on a portion of the surface (capture probes immobilized to silver colloids on substrate, par. 67; capture probes may be antibodies, claim 11) and an opaque layer associated with the portion of the chamber (surface bound silver colloids form substrate, Fig. 1; capture probe immobilized to opaque, silver surface, par. 67). Therefore the products and

methods of making and using the products do not share a corresponding special technical feature.

SPECIES ELECTION

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- **Group A** is drawn to an absence of an apparatus. If group I is elected above **one of the following** absences must be elected from the following species: photomultiplier, wavelength selector, columnator or line voltage.
- **Group B** is drawn to the method of determining the opacity of the metal layer. If group III or IV is elected above, **one of the following** determinations must also be elected from the following species: examining the metal layer with an unaided eye, irradiating the metal layer with light and measuring transmittance or measuring the conductivity of the metal layer.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 26 and 45.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the absent apparatuses of group A are drawn to different structures used for detecting different signal properties. The determinations of group B are drawn to different methods that require structurally different equipment for detection.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 6. The examiner has required restriction between product and process claims.

 Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/ Patent Examiner, Art Unit 1641